

Initially, the Applicants wish to express their sincere appreciation to the Examiner for discussing this application with the patent representatives for the Applicants at an interview on January 12, 1995. During the interview, all of the issues outstanding in connection with the application were discussed. The substance of the discussions is summarized in an EXAMINER INTERVIEW SUMMARY RECORD placed in the file by the Examiner on the date of the interview. It is believed that as a result of the interview and the instant response, this application will be placed in condition for allowance. Again, the Applicants gratefully acknowledge the courtesy of the Examiner in granting the interview concerning the application.

It is initially to be noted that certain amendments have been effected in the claims. Thus, claim 26 has been rewritten as newly formulated claim 31 and claims 27, 28 and 29 are amended to depend from the newly presented claims. The amendments are effected in order to more clearly define the subject matter of the present invention.

In former claim 26, the components of the pharmaceutical composition were individually defined as being present in "a synergistically effective amount". However, it is believed that the term "synergistically effective amount" has relevance, more exactly, with reference to the combination of the components rather than with respect to the individual components. Thus, the language of the claims is amended to specify "a synergistic antimalarially effective amount of a combination of" the components. It is believed that this more clearly defines the pharmaceutical composition of the invention.

Furthermore, the phrase "and pharmaceutically acceptable additives" at the end of the claims has been set apart to further clarify the claimed subject matter.

Claim 30 has been cancelled and replaced by newly formulated claim 32. The purpose of the reformulation of this claim is, again, to more clearly specify that the oral administration is of "a synergistic antimalarially effective amount of a combination of" the components. Again, it is believed that this language will more clearly define the subject matter of the present invention.

Support for the subject matter of the claims as amended is readily apparent from the specification as filed and the patentability of the amended claims will be apparent from the remarks set forth herein.

The claims of the application stand rejected as lacking patentability under the provisions of 35 U.S.C. 103 over Deng et al. (AQ) in view of Wang et al. (R). This ground of rejection is deemed to be untenable and is thus respectfully traversed.

An initial point to be noted is that the Declaration of Bonan Lin previously submitted establishes that the Deng et al. publications which are of record correspond to each other. This Declaration further establishes that only certain information set forth in the publications relates to artemether and benflumetol. An English translation of that information is set forth in the Declaration.

There are two basic failings in the teachings of the Deng et al. publication insofar as the instantly claimed subject matter is concerned. There is no teaching in the publication of a unitary pharmaceutical composition for oral administration containing both benflumetol and artemether. Secondly, there is no suggestion in the publication for the administration of artemether orally.

In the Official Action, the Examiner states:

"To administer artemether orally would have been obvious also, in the absence of evidence to the contrary, as oral administration is the most common form of drug administration."

Following this statement, the Examiner continues with a discussion recognizing that the Declaration of Dr. Wernsdorfer presented with Applicants' PRELIMINARY AMENDMENT of August 18, 1994 states that in 1989 the only envisaged mode of administration of artemether was by the injection intramuscular route. The Examiner urges, however, that the Declaration does not provide an indication of what was known in the art concerning the administration of artemether as of the effective date of invention of the Applicants in August of 1990.

The Applicants believe that there is merit to the position advanced by the Examiner in this regard. A reference publication might have been non-enabling when published and yet might become enabling at some later date prior to an Applicants effective date of invention.

Applicants, however, respectfully submit that this situation did not occur in the present case. Thus, Applicants are submitting herewith the additional Declaration of Dr. Wernsdorfer. This Declaration was discussed in detail with

the Examiner during the recent interview and, prior to the interview, the Examiner was provided - via facsimile - with a copy of the Declaration for consideration prior to the interview.

In this additional Declaration, Dr. Wernsdorfer goes into greater detail concerning the knowledge of the art regarding the development of artemether for the treatment of malaria. The statements of Dr. Wernsdorfer are related - in this Declaration - not to 1989 but to the filing date of the present application. This Declaration makes it clear that at the time of filing of the present application, the oral administration of artemether was not suggested to and would not have been obvious to the art-skilled.

It is believed that this new Declaration of Dr. Wernsdorfer clearly avoids the objection raised by the Examiner in the recent Official Action and clearly establishes the unobviousness of the subject matter being claimed herein.

Based upon the foregoing remarks, and in view of the newly submitted evidence, Applicants respectfully submit that the Examiner's rejection of the claims has been overcome and that the patentability of the instantly claimed subject matter has been clearly established. The Examiner is thus respectfully requested to now reconsider and withdraw the rejection.

In view of all of the foregoing amendments and remarks,
Applicants respectfully submit that the present application is
now in condition for allowance and such allowance is
solicited.

Respectfully submitted,

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January 17, 1995